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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,391	06/04/2007	Phanindrudu Aluri	2006 - 021	1959

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EXAMINER	
YU, HONG	

ART UNIT	PAPER NUMBER
1616	

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12/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,391	ALURI ET AL.	
	Examiner	Art Unit	
	HONG YU	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2009 and 24 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,6,7,16-19 and 22-31* is/are pending in the application.

4a) Of the above claim(s) *2,4,6,7,16-19,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 2, 4, 6, 7, 16-19, and 22-31 are pending, Claims 2, 4, 6, 7, 16-19, 22, and 23 are withdrawn, and claims 1, 3, 5, 8-15, 20, and 21 are canceled in this application. This application is a national stage entry of PCT/IB04/03872, filed on 11/24/2004. This application claims foreign priority to 964/CHE/2003, filed on 11/25/2003 in India and to 930/CHE/2004, filed on 09/17/2004 in India.

Election/Restrictions

Applicants' election without traverse of group II, new claims 24-31, in the reply filed on 05/13/2009 and the correction of non-compliant response filed on 10/24/2009, are acknowledged.

Claims 24-31 will presently be examined to the extent they read on the elected subject matter of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Nijs (WO 01/26621 A2) in view of Meada et al. (EP 1 209 159 A2) and Jerussi (US 6,489,341 B1).

Applicant's claims

Applicants claim a hard compressed oral disintegrable tablet dosage form comprising about 1 to 50% by weight of anhydrous mirtazapine with 90% of the anhydrous mirtazapine particles being less than 400 μm, about 10 to 80% by weight of microcrystalline cellulose as a diluent, and 2 to 15% by weight of crospovidone as a dispersing agent (see claims 24-27).

Claims 28-30 recite the said orally disintegrable tablet dosage form further comprising magnesium stearate as a lubricant, sugar as a sweetening agent, and lemon, orange and peppermint as flavoring agents.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

De Nijs teaches a pharmaceutical composition in form of disintegrating oral tablet comprising mirtazapine (page 2, line 28-30 and page 3, line 17), microcrystalline cellulose as a diluent, crospovidone as a dispersing agent, mannitol and aspartame as

sweetening agents, magnesium stearate as a lubricant, and flavorants (page 9, line 15 and 16).

Ascertainment of the Difference between Scope of the Prior Art and the Claims MPEP 2141.02)

De Nijs does not specify mirtazapine is anhydrous mirtazapine with 90% of the anhydrous mirtazapine particles being less than 400 µm.

This deficiency is cured by Maeda et al. who teach anhydrous mirtazapine with an average particle diameter of from 10 to 50 µm (paragraph 10) being preferable for pharmaceuticals (paragraph 95).

De Nijs does not specify percentages of mirtazapine, diluent, and dispersing agent.

This deficiency is cured by Jerussi who teaches an oral tablet (column 13, line 60-63) comprising 20% by weight of mirtazapine as active agent (table 3 and claim 10), 50 to 90% by weight of a diluent (column 15, line 4-13), and 0.5 to 15% by weight of a dispersing agent (column 15, line 26-36).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP 2142-2143)

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in De Nijs and Maeda et al. to specify mirtazapine with anhydrous mirtazapine with an average particle diameter of from 10 to 50 µm as taught by Maeda et al.. Anhydrous mirtazapine with an average particle diameter of from 10 to 50 µm being preferable in pharmaceutics was well known to a

person of ordinary skill in the art at the time of the invention. It is generally considered to be prima facie obvious to specify a component with a specific particle size which is taught by the prior art to be well known and preferable for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for specifying it flows from it having been used in the prior art, and from it being recognized in the prior art as preferable for the same purpose. As shown by the recited teachings, the instant claims are no more than specifying conventional components of an antidepressant. It therefore follows that the instant claims define prima facie obvious subject matter.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in De Nijs and Jerussi to specify an oral disintegrable tablet comprising 20% by weight of mirtazapine as active agent, 50 to 90% by weight of diluent, and 0.5 to 15% by weight of dispersing agent. Incorporating 20% by weight of mirtazapine as active agent, 50 to 90% by weight of diluent, and 0.5 to 15% by weight of dispersing agent in a disintegrable oral tablet would have been suggested to a person of ordinary skill in the art at the time of the invention. It is generally considered to be prima facie obvious to specify percentages of mirtazapine, a diluent, and a dispersing agent in a disintegrable oral tablet which are taught by the prior art to be well known and useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for specifying them flows from their having been used in the prior art, and from their being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, the instant claims are

no more than specifying percentages of mirtazapine, a diluent, and a dispersing agent in a disintegrable oral tablet. It therefore follows that the instant claims define prima facie obvious subject matter.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over De Nijs (WO 01/26621 A2), Meada et al. (EP 1 209 159 A2), and Jerussi (US 6,489,341 B1) and further in view of tam et al. (US 6,495,154 B1).

Applicant's claims

Applicants claim the said flavoring agents are orange, peppermint, ect.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

The teachings of De Nijs, Meada et al., and Jerussi are discussed above and applied in the same manner.

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

De Nijs does not specify flavor agents are orange and peppermint.

This deficiency is cured by Tam et al. who teach an oral rapid disintegrating tablet comprising mirtazapine and orange oil and peppermint oil as flavorants (column 6, line 60, column 11, line 42-48, claims 52 and 62).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in De Nijs and Tam et al. to specify orange oil and peppermint oil as flavorants. Orange oil and peppermint oil were well known as flavorants to a person of ordinary skill in the art at the time of the invention. It is generally considered to be prima facie obvious to specify components which are taught by the prior art to be well known and useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for specifying them flows from their having been used in the prior art, and from their being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the specifying conventional components of flavorants. It therefore follows that the instant claims define prima facie obvious subject matter.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG YU whose telephone number is (571)270-1328. The examiner can normally be reached on M-Th 8:50 am-6:50 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./
Examiner, Art Unit 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616